



Gharda Chemicals International, Inc.

September 15, 2022

VIA EMAIL

U.S. Environmental Protection Agency
Office of Pesticide Programs
Risk Management and Implementation Branch I (RMIB I)
Attn: Dana Friedman, Branch Chief
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Email: friedman.dana@epa.gov

Re: Gharda Chemicals International, Inc. (EPA Company No. 93182) - Response to EPA's Letter dated August 18, 2022 Regarding (1) Label Consistency with NMFS Biological Opinion on Chlorpyrifos and (2) Label Changes Based on Chlorpyrifos Tolerance Revocations

Dear Ms. Friedman:

On behalf of Gharda Chemicals International, Inc. (Gharda), I submit this response to the letter dated August 18, 2022, from the U.S. Environmental Protection Agency (EPA or Agency) in which you request that Gharda make certain changes to its technical registrations and labels for chlorpyrifos as a result of (1) EPA's revocation of tolerances for chlorpyrifos, and (2) the June 30, 2022, NMFS Biological Opinion (BiOp) (August 18 letter).

With respect to the label issues raised in EPA's August 18 letter relating to tolerance revocation, as you know, on March 30, 2022, Gharda submitted a request for voluntary cancellation of Gharda's food uses of chlorpyrifos **except** the eleven uses in select regions identified in EPA's December 2020 Proposed Interim Decision as critical, high-benefit crop uses (the **Eleven Uses**) (March 30 letter, attached). Gharda said that it is not in a position to voluntarily cancel its registration for the **Eleven Uses**, given the litigation currently pending in the U.S. Court of Appeals for the Eighth Circuit.

Gharda also stated in its March 30 letter that it understands that while the litigation is pending there can be no use, distribution, or sale of chlorpyrifos products for use on food by Gharda, its distributors and dealers, and other downstream users. Gharda suspended the sale and distribution of its chlorpyrifos product labeled for use on food, consistent with EPA's revocation order. Gharda committed in its March 30 letter to working to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA's revocation order remains under review by the Eighth Circuit. Gharda continues that commitment by way of this letter.

Subsequent to Gharda's March 30 letter, it submitted proposed label amendments to the Agency that were consistent with Gharda's letter. However, EPA's August 18 letter states that the

Agency “has reviewed Gharda’s initial submission and has found that it does not fully address concerns about the potential for misbranding due to the lack of chlorpyrifos tolerances.” EPA’s letter does not explain the basis for its concerns. Moreover, in light of (1) Gharda’s March 30 letter requesting voluntary cancellation of all food uses except the **Eleven Uses** and (2) Gharda’s continuing commitment to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA’s revocation order remains under judicial review, it is not clear how the Agency could have reasonable concerns regarding the proposed amendments. Gharda is prepared to discuss further revisions to Gharda’s proposed label amendments, provided any such revisions preserve Gharda’s rights while the tolerance revocation as to the **Eleven Uses** remains under review by the Eighth Circuit.

With respect to EPA’s August 18 letter regarding BiOp-related registration and label amendments, in early June 2022, at EPA’s request, Gharda communicated to the Agency that it accepted the mitigation proposed in the draft revised biological opinion subject to the following: (a) Gharda had no way of determining whether the action contemplated in the final revised BiOp would be relevant to Gharda’s chlorpyrifos registration. Gharda reserved all of its rights in the event that the final revised BiOp did not take into account, or did not accurately take into account, the effect on species resulting from EPA’s Final Rule regarding the revocation of tolerances for food uses of chlorpyrifos and Gharda’s March 30 letter to EPA regarding the voluntary cancellation of certain chlorpyrifos food use registrations and (b) Gharda reserved its rights with respect to the BiOp process pending the outcome in the ongoing litigation in the 8th Circuit regarding chlorpyrifos.

Gharda is still in the process of studying the final BiOp. However, it does not appear that the BiOp took into account the potential retention of the **Eleven Uses** and/or Gharda’s voluntary cancellation of certain chlorpyrifos food uses and, therefore, the BiOp’s mitigation labeling may not be relevant or appropriate as to Gharda’s label. In addition, as noted above, Gharda continues its commitment not to sell the product (even for non-food uses). Under these circumstances, relabeling the product now (for the technical or end-use products) is premature, particularly before the conclusion of judicial review. Again, Gharda is willing to work with the Agency to address any realistic concerns that it has in the most efficient manner possible pending the outcome of the judicial review.

I can be reached at (215) 791-0956 or sramanathan@gharda.com to discuss these issues at the Agency’s convenience.

Respectfully submitted,



Ram Seethapathi
President, Gharda Chemicals International, Inc.

Enclosure

cc: Patricia Biggio biggio.patricia@epa.gov

ATTACHMENT



March 30, 2022

VIA EMAIL

U.S. Environmental Protection Agency
Office of Pesticide Programs
Risk Management and Implementation Branch I (RMIB I)
Attn: Dana Friedman, Branch Chief
1200 Pennsylvania Ave, N.W.
Washington, DC 20460
Email: friedman.dana@epa.gov

Re: Gharda Chemicals International, Inc. (EPA Company No. 93182) - Request for (1) Voluntary Cancellation of Certain Chlorpyrifos Food Use Registrations and (2) Sub-labels for Non-Food Uses

Dear Ms. Friedman:

On behalf of Gharda Chemicals International, Inc. (Gharda), I submit this response to the March 1, 2022 letter of the U.S. Environmental Protection Agency (EPA or Agency), in which EPA requested that Gharda voluntarily cancel registrations and/or uses impacted by EPA's decision to revoke all chlorpyrifos tolerances.

Consistent with its commitment to EPA in the weeks leading up to EPA's Final Rule revoking all chlorpyrifos tolerances, and pursuant to Section 6(f)(1)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Gharda requests voluntary cancellation of the food use registrations identified in Table 1. These uses comprise all of Gharda's currently registered food uses of chlorpyrifos **except** the eleven uses in select regions identified in EPA's December 2020 Proposed Interim Decision as critical, high-benefit crop uses (the **Eleven Uses**).

Table 1: Gharda Chemicals International, Inc. Voluntarily Cancelled Food Uses

Product name	EPA Registration No.	Voluntarily Cancelled Food Uses
Chlorpyrifos Technical	93182-3	Alfalfa (except in AZ, CO, IA, ID, IL, KS, MI, MN, MO, MT, ND, NE, NM, NV, OK, OR, SD, TX, UT, WA, WI, WI), Asparagus (except in MI), Banana, Blueberry, Caneberry, Cherimoya, Citrus Fruits (except in AL, FL, GA, NC, SC, TX), Corn, Cotton (except in AL, FL, GA, NC, SC,

		<p>VA), Cranberries, Cucumber, Date, Feijoa, Figs, Grapes, Kiwifruit, Leek, Legume Vegetables (except soybean), Mint, Onions (dry bulb), Pea, Peanuts, Pepper, Pumpkin, Sorghum, Soybeans (except in AL, CO, FL, GA, IA, IL, IN, KS, KY, MN, MO, MT, NC, ND, NE, NM, OH, OK, PA, SC, SD, TN, TX, VA, WI, WV, WY), Sunflowers, Sugar Beets (except in IA, ID, IL, MI, MN, ND, OR, WA, WI), Sugarcane, Strawberries (except in OR), Sweet Potatoes, Tree Fruit, (apples [except in AL, DC, DE, GA, ID, IN, KY, MD, MI, NJ, NY, OH, OR, PA, TN, VA, VT, WA, WV], pears, cherries [except tart cherries in MI], plums/prunes, peaches [except in AL, DC, DE, FL, GA, MD, MI, NC, NJ, NY, OH, PA, SC, TX, VA, VT, WV] and nectarines), Tree Nuts (almonds, filberts, pecans and walnuts), Vegetables (cauliflower, broccoli, Brussels sprouts, cabbage, collards, kale, kohlrabi, turnips, radishes, and rutabagas), and wheat (except spring wheat in CO, KS, MO, MT, ND, NE, SD, WY and winter wheat in CO, IA, KS, MN, MO, MT, ND, NE, OK, SD, TX, WY).</p>
<p>Pilot 4E Chlorpyrifos Agricultural Insecticide</p>	93182-7	<p>Alfalfa (except in AZ, CO, IA, ID, IL, KS, MI, MN, MO, MT, ND, NE, NM, NV, OK, OR, SD, TX, UT, WA, WI, WI), apple (except in AL, DC, DE, GA, ID, IN, KY, MD, MI, NJ, NY, OH, OR, PA, TN, VA, VT, WA, WV), asparagus (except in MI), brassica (cole), leafy vegetables, radish, rutabaga, turnip, citrus fruits and citrus orchard floors (except in AL, FL, GA, NC, SC, TX), corn (field corn and sweet corn, including corn grown for seed) cotton (except in AL, FL, GA, NC, SC, VA), cranberries figs, grape, legume vegetables (succulent or dried, except soybean), onions (dry bulb), peanut, pear, peppermint and spearmint, sorghum (milo), soybean (except in AL, CO, FL, GA, IA, IL, IN, KS, KY, MN, MO, MT, NC, ND, NE, NM, OH, OK, PA, SC, SD, TN, TX, VA, WI, WV, WY), strawberry (except in OR), sugar beet (except in IA, ID, IL, MI, MN, ND, OR,</p>

		WA, WI), sunflower, sweet potato, almond, walnut (dormant/delayed dormant sprays), tree fruits and almond (trunk spray or preplant dip) tree nuts (foliar sprays) tree nut orchard floors, wheat (except spring wheat in CO, KS, MO, MT, ND, NE, SD, WY and winter wheat in CO, IA, KS, MN, MO, MT, ND, NE, OK, SD, TX, WY), cherries (except tart cherries in MI), and peaches (except in AL, DC, DE, FL, GA, MD, MI, NC, NJ, NY, OH, PA, SC, TX, VA, VT, WV).
Pilot 15G Chlorpyrifos Agricultural Insecticide	93182-8	Citrus and citrus orchards (except in AL, FL, GA, NC, SC, TX), broccoli, Brussel sprouts, cabbage, Chinese cabbage, cauliflower, collards, kale, kohlrabi, broccoli raab, Chinese broccoli, onions, radishes, rutabagas, sweet potatoes, corn, asparagus (except in MI), alfalfa (except in AZ, CO, IA, ID, IL, KS, MI, MN, MO, MT, ND, NE, NM, NV, OK, OR, SD, TX, UT, WA, WI, WI), sorghum, soybeans (except in AL, CO, FL, GA, IA, IL, IN, KS, KY, MN, MO, MT, NC, ND, NE, NM, OH, OK, PA, SC, SD, TN, TX, VA, WI, WV, WY), peanuts, sugar beets (except in IA, ID, IL, MI, MN, ND, OR, WA, WI), turnips, and sunflowers.

Gharda understands that cancellation of the food uses outlined in Table 1 will result in cancellation of the same food uses for the supplemental distribution product identified below in Table 2.

Table 2: Supplemental Distribution Product

Distributor Product Number	Distributor Company Name	Distributor Product Name
93182-7-55467	Tenkoz, Inc.	Govern Insecticide

Gharda understands that a notice of receipt of this voluntary cancellation request will be published in the Federal Register, as required by Section 6(f) of FIFRA. Gharda further understands that the notice may allow up to a 180-day period after publication for public comment, during which time EPA may not approve or reject the request, and that the registrant may request that the comment period be waived. Gharda is not requesting waiver of the comment period. Gharda also understands that it is the Agency's policy to consider comments

received during the public comment period before making its final determination on such a request.

Gharda is not in a position to voluntarily cancel its registration for the Eleven Uses at this time, given the litigation pending in the U.S. Court of Appeals for the Eighth Circuit. Gharda stands prepared to engage in a dialogue with EPA and/or the Department of Justice concerning the Eleven Uses at the appropriate time.

Gharda nevertheless understands that while the litigation is pending there can be no use, distribution, or sale of chlorpyrifos products for use on food by Gharda, its distributors and dealers, and other downstream uses. Accordingly, Gharda has suspended the sale and distribution of its chlorpyrifos product labeled for use on food, consistent with EPA's revocation order. Gharda is also prepared to accept return of its branded product from its distributors and dealers back to its possession and control for relabeling, export, or storage. Gharda is committed to working to ensure that its chlorpyrifos product does not enter the U.S. food supply while EPA's revocation order remains under review by the Eighth Circuit.

With the Agency's permission, Gharda is prepared to submit a request to EPA for sub-labels for its technical and end-use products that would include only non-food uses. This would limit continued domestic distribution, sale, and use of Gharda's relabeled chlorpyrifos products to non-food uses only, consistent with EPA's revocation order. This request is faithful to EPA's revocation order and also preserves Gharda's rights in the ongoing litigation, consistent with the Federal Food, Drug, and Cosmetic Act and FIFRA. Gharda is prepared to work with the Agency on a plan for relabeling consistent with this request.

I can be reached at (215) 791-0956 or sramanathan@gharda.com to discuss these issues at the Agency's convenience.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Ram Seethapathi', with a long horizontal flourish extending to the right.

Ram Seethapathi
President, Gharda Chemicals International, Inc.

CC: Patricia Biggio
Melissa Grable